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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,874	12/11/2001	Edward B. Goldberg	NANF.P-007	4607

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EXAMINER

KAUSHAL, SUMESH

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,874

Applicant(s)

GOLDBERG, EDWARD B.

Examiner

Sumesh Kaushal Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7-24, 46-47 and 49-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 46 is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-24, 47, 49-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Applicant's response filed on 05/19/04 has been acknowledged.

Claims 5-6, 25-45, and 48 are canceled.

Claims 49-65 are newly filed.

Claims 1-4, 7-24, 46-47, 49-65 are pending and are examined in this office action.

Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is **703-872-9306**.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The references cited herein are of record in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 1 and 2 stand rejected under 35 U.S.C. 102(b) as being anticipated by Goldberg (WO 96/11947, 1996) for the same reasons of record as set forth in the office action mailed on 12/18/03.

Claims 1 and 2 are drawn to a purified composition comprising a gp35 or bacteriophage T4 gp35 protein not contained in a gel. Goldberg teaches isolated polypeptide consisting essentially of bacteriophage T4 p35 protein (see page 48, page 55, line 15-36; page 60 lines 1-4). The cited art teaches the isolation of recombinant gp35 protein using standard chromatography techniques including gel filtration and affinity chromatography (page 20). Thus given the broadest reasonable interpretation the cited art clearly anticipate the invention as claimed, since the gp35 as claimed is not limited to a particular amino acid sequence.

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Response to arguments

The applicant argues that the cited art does not teach each and every limitation of the claimed invention. The applicant argues that the cited art does not teach that protein is a nondenatured protein that is obtained in quantity of at least one-microgram and that the protein is not in gel. The applicant argues that it is the specific teaching and not the generic claim language that must be considered.

However, applicant's arguments are found NOT persuasive especially in view of fact that the claims 1 and 2 are generic too, since the gp35 or bacteriophage T4 Gp35 as claimed has not been defined by any structure. As stated above the cited art clearly anticipate the gp35 or bacteriophage T4 Gp35 on page 48-9, disclosing the amino acid sequence of bacteriophage T4 Gp35. Furthermore, the cited art teaches the cited art teaches the isolation of recombinant gp35 protein (non-denatured and in any quantity) using standard chromatography techniques including gel filtration and affinity chromatography (page 20), which has been routine at the time the instant invention was made.

In addition, it is well settled that routine optimization is not patentable, even if it results in significant improvements over the prior art. In support of this position, attention is directed to the decision in *In re Aller, Lacey, and Hall*, 105 USPQ 233 (CCPA 1955): However, even though applicant's modification results in great improvement and utility over the prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art. *In re Sola*, 22 C.C.P.A. (Patents) 1313, 77 F.2d 627, 25 USPQ 433; *In re Normann et al.*, 32 C.C.P.A. (Patents) 1248, 150 F.2d 708, 66 USPQ 308; *In re Irmischer*, 32 C.C.P.A. (Patents) 1259, 150 F.2d 705, 66 USPQ 314. More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Swain et al.*, 33 C.C.P.A. (Patents) 1250, 156 F.2d 239, 70 USPQ 412; *Minnesota Mining and Mfg. Co. v. Coe*, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; *Allen et al. v. Coe*, 77 App. D. C. 324, 135 F.2d 11, 57 USPQ 136. (Emphasis added). Thus given broadest reasonable interpretation the cited art clearly

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anticipate the invention as claimed, since the scope of gp35 as claimed is not limited to a particular amino acid sequence.

Claim Rejections - 35 USC § 112

Claims 1-4, 7-24, 47 and 51-65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the same reasons of record as set forth in the office action mailed on 12/18/03.

Response to arguments

The applicant argues that Goldberg et al the reference cited as prior art discusses the same type of modification, however Goldberg relies on the published sequence for gp35, which is different from SEQ ID NO:2 as claimed. The applicant argues that the scope of genus as claimed lies in proteins having sequences into which conservative substitution have been made, which retains at least one function of the native p35 protein. The applicant argues that specific species embodiments include fragments that consists of amino acid fragments of SEQ ID NO:2. The applicant argues that claims are drawn to these fragments plus additional possible amino acids but the limiting case is these fragments all of which are species disclosed in the application. The applicant argues that the genus as claimed is accordance with written description guidelines.

However, applicant's arguments are found NOT persuasive. As clearly stated in the earlier office action the scope of invention as claimed encompasses a composition comprising any gp35 protein or bacteriophage T4 gp35 protein characterized by any structure/function, since the polypeptides as claimed has not been identified by their structure/function. *Even though the variants as claimed are limited to the amino acid sequence of SEQ ID NO:2, the variant as claimed encompasses a gp35-like protein with one or more [emphasis added] conservative substitutions, or 60% identity to SEQ D NO:2, or comprises at least 8 contiguous amino acids of SEQ ID NO:2, or bound to*

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an antibody directed against gp35 and binds to p36 or p34, or comprises a fragment of SEQ ID NO:2 (see claim 18 and 19) with one or more conservative substitutions, or 30% or 60% identity to amino acid numbers 57-93 of SEQ ID NO:2, wherein the protein has a amino acid terminus that attaches to the C-terminus of bacteriophage T4 p34 protein.

At best the specification only disclose that the amino acid sequence of SEQ ID NO:2 which encodes the bacteriophage T4 gp35 protein. The specification disclosed that the phage T4 gp35 is located between genes gp34 and gp36. The specification further disclosed that two open reading frames ORF34.1 and ORF35 actually connect to form a single ORF35, which encodes a protein of about 40,000 Daltons. The specification further disclosed cloning of ORF35 by PCR of phage DNA between 5'-ATG start codon of ORF34.1 and 3'TAA stop codon of ORF35, which yield a sequence of approximately 1,120 nucleotides in length. However the specification as filed fails to define any variant of gp35 (other than SEQ ID NO:2) which has gp35 like activity explicitly or implicitly as putatively claimed herein. For example the specification fails to disclose that isolated fragments consisting of amino acid sequences of 1-7, 1-56, 1-78, 1-93, 8-17, 57-93, 57-64, 66-79 or 81-93 obtained from SEQ ID NO:2 attach to the C-terminus of bacteriophage T4 p34. Similarly the specification fails to disclose that isolated fragments consisting of amino acid sequences of 1-7, 1-56, 1-78, 1-93, 8-17, 57-93, 57-64, 66-79 or 81-93 obtained from SEQ ID NO:2 comprises a C-terminal gp36 binding domain (all organisms).

The applicant was referred to the guidelines for **Written Description Requirement** published January 5, 2001 in the Federal Register, Vol.66, No.4, pp.1099-1110 (see <http://www.uspto.gov>). The disclosure of a single species is rarely, if ever, sufficient to describe a broad genus, particularly when the specification fails to describe the features of that genus, even in passing. (see *In re Shokal* 113USPQ283(CCPA1957); *Purdue Pharma L. P. vs Faulding Inc.* 56 USPQ2nd 1481 (CAFC 2000). In the instant case the specification only disclose that the amino acid sequence of SEQ ID NO:2 which encodes the bacteriophage T4 gp35 protein. The specification fails to disclose any other variant of SEQ ID NO:2 as putatively claimed

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herein. The possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. See, e.g., *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406; *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991). In the instant case the gp35 or SEQ ID NO:2 variants (as claimed) has been defined only by a statement of function that broadly encompasses a bacteriophage T4 gp35 protein like activity, an affinity for any gp35 antibody or an affinity for bacteriophage T4 gp34 protein or bacteriophage T4 gp34 protein, which conveyed no distinguishing information about the identity of the claimed gp35 protein variants, such as its relevant structural or physical characteristics. Furthermore the variation as claimed also encompasses changes in unknown conserved motifs, since the specification as filed fails to define what are the conserved amino acid sequences which one skill in the art would considered germane for any bacteriophage T4 gp35 protein activity.

Furthermore 40-70% variation (30-60% identity, see claim 20-21) as claimed would certainly affect proper folding and biological activity if amino acids that are critical for such functions are substituted, since the relationship between the sequence of a polypeptide and its tertiary structure is neither well understood nor predictable. Furthermore, mere identification of critical regions would not be sufficient, as the ordinary artisan would immediately recognize that the encoded polypeptide must assume the proper three-dimensional configuration to be active, which is dependent upon the surrounding residues. The specification fails to disclose that isolated fragments consisting of amino acid sequences of 1-7, 1-56, 1-78, 1-93, 8-17, 57-93, 57-64, 66-79 or 81-93 obtained from SEQ ID NO:2 or any variant thereof (as claimed) attach to the C-terminus of bacteriophage T4 p34. Similarly the specification fails to disclose that isolated fragments consisting of amino acid sequences of 1-7, 1-56, 1-78, 1-93, 8-17, 57-93, 57-64, 66-79 or 81-93 obtained from SEQ ID NO:2 or any variant

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thereof (as claimed) comprises a C-terminal gp36 binding domain (all organisms). According to these facts, one skill in the art would conclude that applicant was not in the possession of the claimed genus because a description of only one member of this genus is not representative of the variants of genus and is insufficient to support the claim.

Claims 1-4, 7-24, 47 and 49-65 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for bacteriophage T4 gp35 protein encoded by the amino acid sequences of SEQ ID NO:2, does not reasonably provide enablement for any gp35 protein any bacteriophage T4 gp35 protein or any variant of SEQ ID NO:2 (as claimed) that attaches to the C-terminal of bacteriophage T4 p34 protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Nature of Invention:

The instant invention relates to isolated bacteriophage T4 gp35 protein.

Breadth of Claims and Guidance Provided in the Specification:

The scope of invention as claimed encompasses a composition comprising any gp35 protein or bacteriophage T4 gp35 protein. The scope of invention as claimed further encompasses any variant of amino acid sequences encoding SEQ ID NO:2 with one or more conservative substitution, wherein the variant is capable of that attaching to the C-terminal of bacteriophage T4 p34 protein and/or N-terminal of gp36 protein, or is capable of binding to an antibody that directed against gp35 protein. The scope of variants as claimed further encompasses variants of fragments of SEQ ID NO:2 from amino acid numbers 1-17, 1-56, 1-78, 1-93, 8-17, 57-93, 57-64, 66-79 and 81-93 with one or more conservative substitutions relative to the amino acid sequence of SEQ ID NO:2. The scope of invention as claimed further encompasses variants of a protein encoded by SEQ ID NO: 2 that bind to the p34 protein of bacteriophage T4 or to an antibody directed against any gp35 protein (*not limited to gp35 of bacteriophage T4*) or a ligand. In addition the variants as claimed further encompasses a molecule

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comprising amino acid sequences having at least 30% or 60% identity to amino acid numbers 57-93 in SEQ ID NO:2 over 36 amino acid sequences.

At best the specification only disclose that the amino acid sequence of SEQ ID NO:2 which encodes the bacteriophage T4 gp35 protein. The specification disclosed that the phage T4 gp35 is located between genes gp34 and gp36. The specification further disclosed that two open reading frames ORF34.1 and ORF35 actually connect to form a single ORF35, which encodes a protein of about 40,000 Daltons. The specification further disclosed cloning of ORF35 by PCR of phage DNA between 5'-ATG start codon of ORF34.1 and 3'TAA stop codon of ORF35, which yield a sequence of approximately 1,120 nucleotides in length. However the specification as filed fails to define any variant of gp35 (other than SEQ ID NO:2) which has gp35-like activity explicitly or implicitly as putatively claimed herein. For example the specification fails to disclose that isolated fragments consisting of amino acid sequences of 1-7, 1-56, 1-78, 1-93, 8-17, 57-93, 57-64, 66-79 or 81-93 obtained from SEQ ID NO:2 attach to the C-terminus of bacteriophage T4 p34. Similarly the specification fails to disclose that isolated fragments consisting of amino acid sequences of 1-7, 1-56, 1-78, 1-93, 8-17, 57-93, 57-64, 66-79 or 81-93 obtained from SEQ ID NO:2 comprises a C-terminal gp36 binding domain (all organisms).

State of Art and Predictability

The bacteriophage T4 is one of the archetypical members of the family Myoviridae or T-even phage. These viruses are characterized by a large, elongated icosohedral head; a contractile tail, and tail fibers. The tail fiber proteins have an unusual quaternary structure of long, thin and rigid rods. Their function is to transduce chemical recognition of the E. coli host into a mechanical force on the phage base plate, essentially acting as a set of cooperative levers. This mechanical stress triggers a series of protein conformational changes that lead to entry of the phage DNA into the cell. The three main tail fiber proteins, P34, P36 and P37, are thought to be principally composed of dimeric anti parallel-sheets. Gp35, which forms the angle in the tail fiber, probably has a more complex structure. The joints between the homodimeric segments are also likely to have a more complex structure but there is no evidence that the central

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rod regions have any tertiary structure at all. The extended anti parallel-sheet secondary structure supports the rigid rod quaternary structure. (Hyman et al, PNAS 99(13): 8488-8493, 2002).

The instant application claims variants of the bacteriophage T4 gp35 protein, and provides no distinguishing information about the identity of the claimed variants, such as its relevant structural or physical characteristics. It is general knowledge in the art that even conservative amino acid substitutions can adversely affect proper folding and biological activity if amino acids that are critical for such functions are substituted, and the relationship between the sequence of a polypeptide and its tertiary structure is neither well understood nor predictable. The variants as claimed are mere hypothetical possibilities because no biological functions have been established. The mere identification of critical regions would not be sufficient, as the ordinary artisan would immediately recognize that the encoded polypeptide must assume the proper three-dimensional configuration to be active, which is dependent upon the surrounding residues. Therefore, applicant has not presented enablement commensurate in scope with the claims. see Ngo, in *The Protein Folding Problem and Tertiary Structure Prediction*, Merz et al. (eds.), Birkhauser Boston: Boston, MA, pp. 433 and 492-495, 1994). Rudinger (in *Peptide Hormones*, Parsons (ed.), University Park Press: Baltimore, MD, pp. 1-7, 1976). Therefore it would require an undue amount of experimentation to make and test the all-possible variations for bacteriophage T4 gp35 protein, wherein each variant made has been defined by both structural and functional limitations.

Response to arguments

The applicant argues that the instant application does provide an indication of the size of fragments and area of deletions. The applicant argues that it is known that the N-terminus of p36 attaches to the carboxy terminus of gp35 monomer. The applicant argues that it is unreasonable to expect an applicant test numerous composition to provide person skilled in the art with guidance for avoiding mistakes, rather applicant need to provide guidance as to how to exploit their invention. The applicant argues that the application does provide an indication of the size of the fragment and area that are suitably deleted. The applicant argues that importance of the N-terminus and the C-

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terminus of gp35 in the assembly process is known, therefore use of the variants as claimed is not considered unpredictable.

However, applicant's argument are found NOT persuasive because applicant's argument alone cannot take place of evidence lacking in the record (see *In re Scarbrough* 182 USPQ, (CCPA) 1979). The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). The specification fails to provide any evidence that isolated fragments consisting of amino acid sequences of 1-7, 1-56, 1-78, 1-93, 8-17, 57-93, 57-64, 66-79 or 81-93 obtained from SEQ ID NO:2 attach to the C-terminus of bacteriophage T4 p34. Similarly the specification fails to disclose that isolated fragments consisting of amino acid sequences of 1-7, 1-56, 1-78, 1-93, 8-17, 57-93, 57-64, 66-79 or 81-93 obtained from SEQ ID NO:2 comprises a C-terminal gp36 binding domain (all organisms). The specification fails to provide any evidence that establishes explicitly or implicitly that fragments of SEQ ID NO:2 or any variants of these fragments are capable of binding to C-terminal of T4 gp34 and N-terminal of gp36 (wherein gp36 is obtained from any organism) or to an antibody that recognizes the gp35 protein. As stated above it is general knowledge in the art that even conservative amino acid substitutions can adversely affect proper folding and biological activity if amino acids that are critical for such functions are substituted, and the relationship between the sequence of a polypeptide and its tertiary structure is neither well understood nor predictable. Under the law, the disclosure "shall inform how to use, NOT how to find out how to use for themselves." See *In re Gardner* 475 F.2d 1389, 177 USPQ 396 (CCPA 1973). The bacteriophage T4 gp35 protein which forms the angle in the tail fiber is known to have a complex structure and without sufficient guidance to make a specific mutation in the disclosed amino acid sequences the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). It is noted that the unpredictability of a particular area may alone provide reasonable doubt as to the accuracy of the broad statement made in support of enablement of claims. See *Ex parte Singh*, 17 USPQ2d 1714 (BPAI 1991).

Therefore, one skill in the art would have to engage in excessive and undue amount of experimentation to exercise the invention as claimed.

Conclusion

Claims 1-4, 7-24, 47 and 49-65 are rejected.

Claim 46 is allowed.

Claims 49-50 dependent upon a rejected base claim(s), but would be allowable if rewritten independent form including all of the limitation of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 571-272-0769. The examiner can normally be reached on Mon-Fri. from 9AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yucel Irem Ph.D. can be reached on 571-272-0781.

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Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to **(571) 272-0547**. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199. The fax phone number for the organization where this application or proceeding is assigned is **703-872-9306**.

Sumesh Kaushal
Examiner GAU 1636


JEFFREY FREDMAN
PRIMARY EXAMINER
10/17/07